(Unofficial)

Notification of Ministry of Public Health

(No. 293) B.E.2548 (2005)

Re. Food Supplement

To protect consumers from consuming food supplement products and prescribed conditions of giving correct information due to technical basis.

By the virtue of the provisions of Sections 5 and 6 (3) (4) (5) (6) (7) and (10) of the Food Act B.E. 2522 (1979), in which contain provisions in relation to the restriction of Rights and Liberties of the persons, in respect of which Section 29 and in conjunction with 35, Section 39, Section 48 and Section 50 of the Constitution of the kingdom of Thailand so permit by virtue of provisions of law; the Minister of Public Health hereby issues a notification as follows;

Clause 1. The notification of the Ministry of Public Health No.242 B.E. 2544 (2001), Re: Garlic products, dated 26 th September B.E. 2544 (2001) shall be repealed.

Clause 2. Food supplement means products taken for consume other than conventional foods which contain nutrients or other substances as ingredients, are in forms of tablets, capsules, powders, flakes, liquids or others ; which are not conventional foods for consumers who expect for benefit of health promotion.

Clause 3. This notification, nutrients or other substances mean :

(1) Vitamins, amino acids, fatty acids, minerals and produces obtained from plants or animals.

- (2) Concentrates, metabolites composition or extracts of substances of (1).
- (3) Artificial substances imitated like substances of (1) or (2).
- (4) Mixtures of one or more of substances of (1) (2) or (3).

(5) Substances or others as to Food and Drug Administration prescribed according to an approval of the Food Committee.

Clause 4. Food supplement are prescribed to be the food subject to the qualities or standards and label shall be approved before use.

To apply for label approval before use shall be proceeded as follows:

(1) Submit for food registration; for food supplement which manufactured to export or food supplement which contain main ingredients that the Food and Drug Administration prescribed according to an approval of the Food Committee.

(2) Submit for label approval for food supplement which contain active ingredients other than prescribed in (1) by present evidences and documents for label approval permission that the Food and drug administration prescribed according to an approval of the Food Committee.

Clause 5. Food Supplement shall be of qualities or standards as follows:

(1) Have specific characteristics due to those kinds of products;

(2) Pathogenic bacteria shall be detected not more than limits that the Food and Drug Administration prescribed according to an approval of the Food Committee.

(3) *Escherichia coli* shall be detected less than 3 per 1 g of food by Most Probable Number method;

(4) Microbial toxins, pesticide residues, other toxic substances, contaminants or veterinary drug residues shall be detected not more than limit prescribed in Notification of Ministry of Public Health for those in each case;

(5) Vitamin or mineral content shall not be less than 15% and not exceed the maximum specified in nutrient list for Thai Recommended Daily Intakes for age of 6 years and up (Thai RDI) for food supplements whose purpose as to give vitamins or minerals. For vitamins or minerals are not prescribed, the Food and Drug Administration shall prescribed according to an approval of the Food Committee.

Clause 6. Usage of Food Additives shall follow to the Notification of Ministry of Public Health, Re : Food Additives.

Clause 7. Food supplement producers or importers for sale shall follow to the Notification of Ministry of Public Health, Re: Production processes, production equipments, and food storages.

Clause 8. Use of packaging for food supplement shall follow to the Notification of Ministry of Public Health, Re : Packaging.

Clause 9. Labeling of food supplement shall follow to the Notification of Ministry of Public Health, Re : Label, except clause 3 and 5 of the Notification of Ministry of Public Health (No. 194) B.E.2543 (2000) Re: Label dated 19th September B.E.2543 (2000) which is amended by the Notification of Ministry of Public Health (No. 252) B.E.2545 (2000) Re: Label (No.2) dated 30th May B.E.2545(2000) shall follow Clause 10 and 12 instead.

Clause 10. Labeling of food supplement products for sale to consumers shall be expressed in Thai language text but foreign language text may also be presented; and shall have texts to express as follows:

(1) Names of food, "food supplements" shall be displayed as a part of the name, or accompanied with.

(2) Food serial number.

(3) Name and address of producers or importers, as the case may be, as follows:

(3.1) For food produced within country, name and address of producers or re-packers for sale shall be displayed, or name and address of head office of producers or re-packers may be displayed instead.

(3.2) For imported food, name and address of importer and country of producer;

(4) Food supplement quantities shall be expressed as the case may be, as follows:

(4.1) Food supplement in form of tablets or capsules expressed as the number per pack.

(4.2) Food supplement in form of liquid expressed as net volume.

(4.3) Food supplement in form of solid or others expressed as net weight.

(5) Name and quantity of main ingredients of food supplement and constituents which claims for usefulness, on the label of food supplement .

(6) Declaration of "utilizing preservatives" (if any)

(7) Declaration of "natural colour added" or "artificial colour added" if utilizing, as case may be

(8) Declaration of "natural fragrance", "imitation natural fragrance", "synthetic fragrance", "natural flavour", or "imitate natural flavour" if any, as case may be.

(9) Clear statement of "Receiving any nutrients should intake by consuming five categories of principle foods and in appropriate proportion.

(10) Instruction for use.

(11) Instruction for food storage. (if any)

(12) Date, month, and year of expiration for consumption or date, moth, and year in which

food is in good qualities or standards for food supplement with minimum durability of not more than 90 days; or month, and year of expiration for consumption or , moth, and year in which food is in good qualities or standards for food supplement with minimum durability of more than 90 days; and shall incorporated with declarations of "Produce", "Expire", or "Consume before", as the case may be; and date, month, and year shall be respectively expressed.

The declarations, according to (12) under the packaging, on the label shall present statement which indicate the position of that declaration.

(13) Warning of food supplement consuming shall be followed the Notification of the Ministry of Public Health, Re : Health claim and Warning of food consuming.

Clause 11. The declaration of Health claim on label shall follow to the notification of the Ministry of Public Health, Re: Health claim of food and warning of food consuming.

Clause 12. Label of food supplement which are not for sale to consumers shall be expressed in Thai language text, except for imported food supplement may be expressed in English language text, and at least the text shall be expressed the details presented in 10(1)(2)(3) and (4).

Clause 13. Producers, importers of "Garlic products" or "Food supplement", whose permit for Label issued prior to this notification come into force, if details do not follow this notification shall be amended within two years after this notification come into force, and the remaining labels are allowed to be used but not exceeding to 2 years after this notification come into force.

Clause 14. This notification shall come into force after 90 days as from the day following date of its publication in the Government Gazette.

Notified on 15th December 2005.

Signed Anuthin Chanverakool (Mr.Anuthin Chanverakool) Deputy Minister of Public Health acting for Minister of Public Health ecial Part 150 Ngor, dated 28th December 200

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Certified true copy Varunee Sensupa (Miss Varunee Sensupa) Food and Drug Specialist level 8

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.